protocol registration process. Final IBC approval may then be granted.

RAC meetings will be open to the public except where trade secrets or confidential commercial information are reviewed. To enable all aspects of the protocol review process to be open to the public, information provided in response to Appendix M–I–A should not contain trade secrets or confidential commercial or financial information. Documentation submitted to the NIH OSP shall not be designated as 'confidential' in its entirety. In the event that a determination has been made that a specific portion of a document submitted should be considered as proprietary or trade secret, each specific portion should be clearly identified as such. The cover letter (attached to the submitted material) shall: (1) Clearly indicate what select portions contain information considered as proprietary or a trade secret; and (2) provide justification as to why this information is considered to be proprietary or trade secret. This justification must be able to demonstrate *with specificity* how release of that information will reveal a trade secret or will result in substantial competitive harm.

Appendix M–I–C–2 currently states:

Appendix M–I–C–2. Additional Clinical Trial Sites

No research participant shall be enrolled (see definition of enrollment in Section I–E–7) at a clinical trial site until the following documentation has been submitted to NIH OBA: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; (4) curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

Appendix M–1–C–2 will be amended as follows:

Appendix M–I–C–2. Additional Clinical Trial Sites

Within 30 days of enrollment (see definition of enrollment in Section I–E–7) at a clinical trial site, the following documentation shall be submitted to NIH OSP: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; and (4) NIH grant number(s) if applicable.

There are no amendments to Appendix M–I–D, Safety Assessments in Human Gene Transfer Research.

The current appendices Appendix M–II, Description of the Proposal; Appendix M–III, Informed Consent; Appendix M–IV, Privacy; and Appendix M–V, Special Issues will be deleted in their entirety, except for Appendix M–III–B–2–b, Long Term Follow-Up which will be updated to include a reference to FDA's current guidance on this issue and will become Appendix M–II.

Appendix M–II will be amended as follows:

Appendix M–II. Long Term Follow-Up

To permit evaluation of long-term safety and efficacy of gene transfer, prospective subjects should be informed that they are expected to cooperate in long-term follow-up that extends beyond the active phase of the study. A list of persons who can be contacted in the event that questions arise during the follow-up period should be provided to the investigator. In addition, the investigator should request that subjects continue to provide a current address and telephone number.

The subjects should be informed of any significant findings resulting from the study will be made known in a timely manner to them and/or their parent or guardian including new information about the experimental procedure, the harms and benefits experienced by other individuals involved in the study, and any long-term effects that have been observed.

Additional guidance is available in the FDA Guidance for Industry: Gene Therapy Clinical Trials—Observing Subjects for Delayed Adverse Events (available at the following URL: *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/default.htm).*

Appendix M–VI Footnotes of Appendix M will be renumbered to Appendix M–III. Footnotes of Appendix M. There will be no amendment to the language.

Dated: March 15, 2016.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2016–06448 Filed 3–21–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

This meeting is open to the public but is being held by teleconference only. No physical meeting location is provided for any interested individuals to listen to and/or participate in the meeting. Any individual interested in listening to the meeting discussions must call 800–779–9040 and use Participant Passcode 5055308 for access to the meeting. Individuals needing special assistance should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: April 21, 2016.

Time: 4:00 p.m. to 6:00 p.m. EDT.

Agenda: The HeLa Genome Data Access working group will report on the evaluation of requests to access HeLa cell genome sequence data. The Clinical Center working group will present their final report to the Advisory Committee to the Director, NIH.

Place: National Institutes of Health, (Telephone Conference Call), Dial In Number 800–779–9040, Participant Passcode: 5055308.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, Telephone: 301–496–4272, Email: *woodgs@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding their statement electronically to the Contact Person at *woodgs@od.nih.gov.* The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested of the interested person.

Additional information for this meeting including both working group reports will be posted, when available, on the Advisory Committee to the Director, NIH, Web site (*http://acd.od.nih.gov*). Additional information about the HeLA Genome Data Access working group is available at *http://acd.od.nih.gov/hlgda.htm* and additional information about the Clinical Center working group is available at *http://acd.od.nih.gov/redteam.htm.*

Dated: March 15, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06333 Filed 3–21–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review, Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,